PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Application of:	)	
	)	Atty. Docket No. PC10833A
Thombre et al.	)	
	)	Art Unit: 1615
Serial No.: **10/091,202**	)	
	)	Examiner: Susan T. Tran
Filed: **March 5, 2002**	)	
	)	Conf. No.: 6366

For: **Palatable Pharmaceutical Compositions for Companion Animals**

BRIEF ON APPEAL

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BRIEF ON APPEAL

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Commissioner for Patents
P.O. Box 1450
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Dear Sir:

An original and three copies of this appeal brief are submitted along with the large entity fee of five hundred dollars ($500) for filing an appeal brief. In the event of any variance between any of the amounts enclosed and the Patent and Trademark Office charges, the Commissioner is authorized to charge or credit any difference to our Deposit Account No. 21-0718.

Contents

REAL PARTY IN INTEREST

The real party in interest is Pfizer Inc., New York, New York, to whom this invention is assigned.

RELATED APPEALS AND INTERFERENCES

Applicant is aware of no related appeals or interferences concerning this application.

STATUS OF CLAIMS

At final rejection:

claims 7-8, 28-29, and 39 were cancelled;

claims 1-6, 9-27, 30-38, and 40-46 were pending;

claims 11, 12, 16-18, 41, and 43-46 were withdrawn from consideration; and

claims 1-6, 9, 10, 13-15, 19-27, 30-38, 40 and 42 were rejected, which rejections are appealed from.

A clean set of the claims as pending upon final rejection is attached in Appendix A.

STATUS OF AMENDMENTS

An amendment after final was filed on August 23, 2004. On October 1, 2004, the Examiner issued an Advisory Action refusing to enter the proposed amendment as presenting additional claims without canceling a corresponding number of finally rejected claims. As of the filing of this Appeal Brief, the after-final amendment had not yet been entered. However, because the amendments would reduce the number of issues on appeal, the applicants expect the after-final amendment will be entered and, therefore, have limited the arguments in this Appeal Brief to the issues remaining after entry of the

amendments. A clean copy of the claims as sought to be amended by the after-final amendment is attached as Appendix B. A marked-up copy of these claims, showing the after final amendments sought, is attached in Appendix C.

SUMMARY OF THE INVENTION

The invention relates generally to palatable pharmaceutical compositions that can be administered orally to companion animals. Page 1, lines 3-4. In one of its aspects, the invention relates to a palatable pharmaceutical composition comprising a pharmaceutically active agent in combination with a palatability improving agent and a pharmaceutically acceptable carrier. Page 4, lines 14-16. The palatability improving agent is non-meat and non-fish derived, and includes artificial egg, artificial beef, artificial poultry, artificial fish, dairy based palatability improving agent and natural herbs and spices and mixtures thereof. Page 4, lines 16-17 and 31-33. In another of its aspects, the invention relates to a palatable pharmaceutical composition comprising a pharmaceutically active agent, one or more excipients, and a palatability improving agent, wherein the palatability improving agent is a yeast or yeast hydrolysate or combination thereof, and wherein the agent is present in an amount ranging from about 2 % by weight to about 25 % by weight of the pharmaceutical composition. Page 5, lines 18-24. In another of its aspects, the invention relates to a method of making a pharmaceutical composition that is palatable to a companion animal. Page 12, lines 3-14.

ISSUES

The issues presented to the Board are those remaining after entry of the after-final amendment, a copy of which is attached at Exhibit B (clean version) and Exhibit C (marked up version):

I. Whether claims 13 and 14 are unpatentable under 35 U.S.C. § 112, second paragraph, as indefinite;

II. Whether claims 1, 9, 10, 13-15, 19-21, 24-27, 30, 31, 33-35 and 42 are unpatentable under 35 U.S.C. §102(b), as anticipated by U.S. Patent 4,681,758 ("Fruthaler");

III. Whether claims 1, 13, 14, 19-21, 24-27 and 30-35 are unpatentable under 35 U.S.C. §102(b), as anticipated by U.S. Patent 4,118,512 ("Eichelburg");

IV. Whether claims 1, 9, 10, 13-15, and 42 are unpatentable under 35 U.S.C. §102(b), as anticipated by U.S. Patent 5,824,336 ("Jans");

V. Whether claims 1-6, 9-10, 13-15, 19-27, 30-37, 40 and 42 are unpatentable under 35 U.S.C. §103(a), over Eichelburg, in view of U.S. Patent 5,224,989 ("Likarova") and U.S. Patent 6,506,785 ("Evans");

VI. Whether claims 1-6, 9-10, 13-15, 19-27, 30-38, and 42 are unpatentable under 35 U.S.C. §103(a), over Eichelburg in view of Jans; and

VII. Whether the Office Action of March 23, 2004 was properly made final.

GROUPING OF THE CLAIMS

Claims 13 and 14 stand or fall together. See Section I below.

Claims 1, 9, 10, 13-15, 19-21, 24-27, 30, 31, 33-35 and 42 stand or fall together. See Section II below.

Claims 1, 13, 14, 19-21, 24-27 and 30-35 stand or fall together. See Section III below.

Claims 1, 9, 10, 13-15, and 42 stand or fall together. See Section IV below.

Claims 1-6, 9-10, 13-15, 19-27, 30-37, 40 and 42 stand or fall together. See Section V below.

Claims 1-6, 9-10, 13-15, 19-27, 30-38, and 42 stand or fall together. See Section VI below.

ARGUMENT

I. Claims 13 and 14 are definite under 35 U.S.C. § 112, second paragraph

Claims 13 and 14 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully submit that the rejection is overcome by the after-final amendment.

The Examiner alleges that there is insufficient antecedent basis in claims 13 and 14 for the limitation "wherein the palatability improving agent is yeast." Claims 13 and 14, as amended by the after-final amendment, depend on claim 19 in which yeast is claimed as a palatable improving agent. The objected to limitation, therefore, does not lack antecedent basis. Applicants respectfully request withdrawal of the rejection.

II. Claims 1, 9, 10, 13-15, 19-21, 24-27, 30, 31, 33-35 and 42 are not anticipated by Fruthaler under 35 U.S.C. §102(b)

Claims 1, 9, 10, 13-15, 19-21, 24-27, 30, 31, 33-35 and 42 stand rejected under 35 U.S.C. §102(b) as being anticipated by Fruthaler. Applicants respectfully submit that the rejection is overcome by the after-final amendment.

Under 35 U.S.C. § 102, a claim is anticipated only if each and every element as set forth in the claim is found in a single art reference. *Verdegaal Bros. v. Union Oil Co.*, 2 USPQ2d 1051, 10533 (Fed. Cir. 1987); *In re Recombinant DNA Technology Patent and Contract Litigation*, 30 USPQ2d 1881, 1885 (S.D. Ind.1993) ("A patent is anticipated only if all the elements and limitations of the claims are found within a single, prior art reference."); *Structural Rubber Products Co. v. Park Rubber Co.*, 223 USPQ 1264, 1270 (Fed. Cir. 1984) (All elements of the claimed invention must be contained in a single prior art disclosure and must be arranged in the prior art disclosure as in the claimed invention); M.P.E.P § 2131. Furthermore, no difference may exist between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of invention. *In re Recombinant DNA Technology Patent and Contract Litigation*, 30 USPQ2d 1881, 1885 (S.D. Ind.1993). Also, the identical invention must be described or shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); *Chester v. Miller*, 15 USPQ2d 1333 (Fed. Cir. 1990); M.P.E.P. § 2131.

Claims 1, 9, 10, 13-15, 19-21, 24-27, 30, 31, 33-35 and 42, as amended by the after-final amendment, specify that the pharmaceutically active agent is carprofen. This limitation is not disclosed in Fruthaler. Fruthaler, therefore, does not disclose every element of the claimed invention.

Claims 1, 9, 10, 13-15, 19-21, 24-27, 30, 31, 33-35 and 42 are not anticipated by Fruthaler because Fruthaler does not disclose every element of the claimed invention. Withdrawal of the rejection is respectfully requested.

III. Claims 1, 13, 14, 19-21, 24-27 and 30-35 are not anticipated by Eichelburg under 35 U.S.C. § 102(b)

Claims 1, 13, 14, 19-21, 24-27 and 30-35 stand rejected under 35 U.S.C. §102(b) as being anticipated by Eichelburg. Applicants respectfully submit that the rejection is overcome by the after-final amendment.

Claims 1, 13, 14, 19-21, 24-27 and 30-35, as amended by the after-final amendment, specify that the pharmaceutically active agent is carprofen. This limitation is not disclosed in Eichelburg. Eichelburg, therefore, does not disclose every element of the claimed invention.

Claims 1, 13, 14, 19-21, 24-27 and 30-35 are not anticipated by Eichelburg because Eichelburg does not disclose every element of the claimed invention. Withdrawal of the rejection is respectfully requested.

IV. Claims 1, 9, 10, 13-15, and 42 are not anticipated by Jans under 35 U.S.C. §102(b)

Claims 1, 9, 10, 13-15, and 42 stand rejected under 35 U.S.C. §102(b) as being anticipated by Jans. Applicants respectfully submit that the rejection is overcome by the after-final amendment.

Claims 1, 9, 10, 13-15, and 42, as amended by the after-final amendment, specify that the pharmaceutically active agent is carprofen. This limitation is not disclosed in Jans. Jans, therefore, does not disclose every element of the claimed invention.

Claims 1, 9, 10, 13-15, and 42 are not anticipated by Jans because Jans does not disclose every element of the claimed invention. Withdrawal of the rejection is respectfully requested.

V. Claims 1-6, 9-10, 13-15, 19-27, 30-37, 40 and 42 are not unpatentable under 35 U.S.C. §103(a) over Eichelburg, in view of Likarova and Evans

Claims 1-6, 9-10, 13-15, 19-27, 30-37, 40 and 42 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Eichelburg, in view of Likarova and Evans. Applicants respectfully disagree with the rejection.

The Federal Circuit has reiterated the manner in which obviousness rejections are to be reviewed. "A proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991), citing *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988). As the Federal Circuit emphasized by succinctly summarizing: "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the Applicants' disclosure." *Id.* Applicants respectfully submit that the prior art cited by the Office

would not have suggested to those of ordinary skill in the art that they should pursue the claimed invention.

The Office admits that Eichelburg does not teach the palatability-improving agent is artificial meat. Final Office Action of March 23, 2004, page 5. The Office, however, states that Likarova teaches film-forming compositions suitable for veterinary medicine, where the film-forming composition comprises artificial meat or milk flavor in addition to other attractants and lurants. The Office then states that it would have been obvious for one of ordinary skill in the art to modify Eichelburg's oral animal medicine composition using the film-forming attractant flavors in view of the teachings of Likarova.

Eichelburg relates to compositions that concern yeast hydrolyzate oral ingesta for animals, where oral ingesta such as animal medicament or animal food is combined with either hydrolyzates of Torulopsis utilis or Saccharomyces cerevisiae. Eichelburg states:

> The prior art discloses that yeast may be employed in animal food in concentrations up to about 0.5% as a B vitamin supplement; however, when yeast is used in admixture with animal food in such low concentrations it has no effect on improving the palatability of the animal food. Applicant has established by experiments that such animal food whether dry animal food or moist animal food described in U.S. Pat. Nos. 3,119,691 Ludington et al. and 3,202,514 Burgess et al. either have minimal palatability as dry animal food or lose palatability as in the case of moist animal food, but such palatability can be greatly enhanced by the use of greater than 0.5% by weight of yeast hydrolyzate as a coating on such animal food.

Eichelburg, col. 8, line 66 to col. 9, line 11, emphasis added.

Eichelburg further provides: "When the yeast hydrolyzate is employed in admixtures with the ingesta, palatability will be reduced by virtue of the dilution effect of the ingesta on the yeast hydrolyzate. Consequently, slightly higher concentrations of the

yeast hydrolyzate are preferred when it is combined with ingesta as an admixture." Eichelburg, col. 10, lines 22-27, emphasis added. Applicant did not find within Eichelburg the preferred amount of yeast when admixing, but Example 2 provides that 0.25 oz of yeast was admixed with 0.0125 oz of piperazine adipate. See col. 10, lines 49-59.

Moreover, Eichelburg concerns yeast, not artificial beef. Indeed, when discussing a problem to be solved, Eichelburg at col. 2, lines 20-29 (emphasis added) indicates that admixing food with beef extract does not work:

> The prior art also teaches improvement in the palatability of dry animal food kibs by the addition of liquid beef extract such as beef broth or fish scrap. It has been observed, however, that even with the addition of liquid beef extracts, such as beef broth or fish scrap, to standard commercially-prepared dry animal food kibs, the resultant dry animal food kib does not have sufficient palatability to induce an animal to eat sufficient amounts of the animal food to maintain proper nutrition.

Likarova relates to a film forming dispersion containing essentially acetylester of oxidized starch and triethylcitrate useful for surface protection of drug and food containing tablets, pellets, pills, granules or their components in crystalline form, especially those containing one or more active substances and ingredients. Likarova, col. 1, lines 10-16. Likarova states:

> It is, therefore, a primary object of this invention to provide a film-forming dispersion which would effectively protect core containing active ingredient without submitting the core to undesirable contact with water for extended period of time as well as to high temperature, pressure, and aeration. The current invention concerning a novel type of protective coating avoids all these undesirable exposures while resulting in effective, desirable, safe and economical protective coating for drug and food containing articles and objects.

Likarova, col. 2, lines 45-54, emphasis added.

As noted by Applicant in the Response to the Office Action of March 13, 2003, Likarova's palatability agents are formed as films, not admixed with the active ingredient, as presently claimed. Likarova concerns films which "may" contain artificial meat or milk flavor or some other attractants or lurants for veterinary medicine. Likarova, col. 5, line 32. Likarova does not teach, motivate or suggest the use of artificial meat for anything but a coating.

When reading Eichelburg as a whole, it teaches away from the relatively low amount of yeast used in the present invention - that amount being 2 % to 25 % - for admixing. Eichelburg concerns yeast for coating and admixing. Neither Likarova nor Eichelburg suggest that they should be combined and they both suggest coating is preferred. The general discussion therein would not suggest that one of ordinary skill in the art would so combine to give the pending invention. The references as a whole do not suggest the likelihood of success with the exact invention claimed in the pending application. The references are inappropriately being combined based on the disclosure of the pending application. *In re Vaeck*, supra.

Evans relates to the use of carprofen in mammals for the treatment and prevention of cartilage and subchondral bone injury and loss. Evans, col. 1, lines 9-12. The Office states that Likarova teaches ibuprofen tablets having an artificial flavor coated. The Office further states that it thus would have been obvious for one of ordinary skill in the art to optimize the palatable dosage form of Eichelburg and Likarova using carprofen as a medicament agent in view of the teaching of Evans with the expectation of providing an improved palatable dosage form comprising a medicament suitable for companion animal.

As already discussed, Likarova or Eichelburg do not suggest or motivate that they should be combined. The addition of Evans does not affect this reasoning. Evans does not suggest or motivate the combination of all three references. The general discussions in all references do not suggest that one of ordinary skill in the art would so combine. The references as a whole do not suggest the likelihood of success with the exact invention claimed in the pending application. Indeed, the references actually teach away from the claimed invention. The references are inappropriately being combined based on the disclosure of the pending application. *In re Vaeck, supra.* References may not merely be combined to add the elements together. There needs to be motivation or suggestion to so combine with expectation of success of the combination of elements. As discussed, the references do not so motivate or suggest such a combination.

Applicants respectfully submit that the cited references do not provide the teaching, suggestion, or motivation that would lead a person of ordinary skill in the art to the claimed invention.

The Office also states that the limitation "wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 50% voluntary acceptance" in claims 2-6 is inherent because Eichelburg teaches the use of the same materials to obtain the same result desired by the applicant. Claim 1 concerns palatable agents where the agent is artificial beef. The Office states that Eichelburg does not teach the palatability-improving agent is artificial beef. Final Office Action of March 23, 2004, page 5. Hence, Eichelburg cannot teach the use of the "same materials" as claims 2-6, as stated by the Office. Applicant respectfully requests the withdrawal of this rejection.

VI. Claims 1-6, 9, 10, 13-15, 19-27, 30-38 and 42 are not unpatentable under 35 U.S.C. §103(a) over Eichelburg in view of Jans

Claims 1-6, 9, 10, 13-15, 19-27, 30-38 and 42 stand rejected as being unpatentable over Eichelburg in view of Jans. The Office contends that Jans teaches a chewable tablet having a hardness of 100 Newtons, not disclosed by Eichelburg. From this, the Office concludes that it would have been obvious to combine Eichelburg and Jans to arrive at the claimed invention because the references teach the advantageous results in the use of "similar ingredients" to obtain an improved palatability composition for companion animals. Final Office Action of March 23, 2004, page 7. Applicants disagree.

As discussed above, the Office admits that Eichelburg does not disclose artificial beef. The compositions in Jans "always contain large amounts of brewer's yeast." Jans, col. 1, lines 66-67. The compositions of the present invention do not always contain yeast. The references do not have "similar ingredients." This rejection should not be allowed to stand against at least claims 1-6, and 9-10 because said claims contain artificial beef as the palatable agent. The references do not concern and do not motivate or suggest the claimed invention wherein the palatable agent is artificial beef.

Regarding the remaining rejected claims, the compositions in Jans have yeast in addition to a flavouring agent. The broadest range of yeast found by Applicant in Jans is 40% to 70%. Jans, col. 4, line 65. The preferred compositions comprise by weight based on the total weight of the composition: flubendazole, from 22% to 33%; brewer's yeast,

from 50% to 65%; hydroxypropyl methylcellulose, from 2% to 3%; and flavouring agents, from 0.1% to 0.2%. Jans, col 3, lines 14-20.

As previously discussed, Eichelburg discloses the need for more yeast when admixing with the active ingredient. Although several ranges are provided in Eichelburg (col. 11, lines 2745), Example 2 indicates that the amount is high in an admixture (0.25 oz yeast and 0.0125 oz piperazine adipate). The percent of yeast for coating is 12% and 10% by weight for Examples 1 and 3, respectively.

The pending application has yeast being from about 2% to about 25% by weight. The combined references teach away from this percent of yeast or yeast hydrolysate in the pending application. Although the word yeast may appear in the references, the references, taken as a whole, teach away from the claimed invention. Furthermore, the general discussions within the references do not suggest or motivate one of ordinary skill in the art to combine them to result in the invention claimed in the pending application. Withdrawal of the rejection is therefore respectfully requested.

VII. The Office Action of March 23, 2004 Should Not Have Been Made Final

Applicants object to the finality of the March 23, 2004 Office Action.

Under MPEP 706.07(a), a final rejection is proper where the Examiner introduces a new ground for rejection necessitated by applicant's amendment of the claims. See MPEP 706.07(a). However, "a second or any subsequent action on the merits in any application . . .will not be made final if it includes a rejection, on newly cited art . . . of any claim not amended by applicant . . . in spite of the fact that other claims may have been amended to require newly cited art." Id.

The March 23, 2004 Office Action cites Evans, U.S. Patent 6,506,785, a new reference not previously cited by the Office. The Office also makes new arguments based on this reference. It is believed that the new art and arguments are not based on any amendments made by Applicants. Therefore, the Office Action should not have been made final. Applicant respectfully requests the withdrawal of the finality of the March 23, 2004 Office Action.

Summary

On the basis of the foregoing and in view of the arguments presented herein, reversal of each and every rejection is appropriate.

Respectfully submitted,

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APPENDIX A

Claims at Final Rejection

1. (previously presented) A palatable pharmaceutical composition for oral administration to companion animals comprising a pharmaceutically effective amount of a pharmaceutically active agent in combination with a palatability improving agent and a pharmaceutically acceptable carrier, wherein the palatability improving agent is selected from the group consisting of artificial egg, artificial beef, artificial poultry, artificial fish, dairy based palatability improving agent and natural herbs and spices, or mixtures thereof, is present in amounts sufficient to make the pharmaceutical composition palatable to the companion animal, and is homogeneously mixed with the pharmaceutically active agent.

2. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 30% voluntary acceptance.

3. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 50% voluntary acceptance.

4. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 80% voluntary acceptance.

5. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 90% voluntary acceptance.

6. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal of about 90% or greater.

7-8. (canceled)

9. (original) The pharmaceutical composition according to claim 1 wherein the pharmaceutically active agent has an unacceptable taste and the palatability improving agent is present in amounts sufficient to mask or improve the unacceptable taste of the pharmaceutically active agent.

10. (original) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is present in an amount ranging from about 0.025% to about 99% by weight of the pharmaceutical composition.

11. (withdrawn) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is not yeast and is present in an amount ranging from about 0.075% to about 50% by weight of the pharmaceutical composition.

12. (withdrawn) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is not yeast and is present in an amount ranging from about 1% to about 25% by weight of the pharmaceutical composition.

13. (original) The composition of claim 1 wherein the palatability improving agent is yeast and is present in an amount ranging from about 2% to about 25% by weight of the pharmaceutical composition.

14. (original) The composition of claim 1 wherein the palatability agent is yeast present in an amount ranging from about 5% to about 20% by weight of the pharmaceutical composition.

15. (previously presented) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is an artificial egg, artificial beef, or artificial poultry.

16. (withdrawn) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is a mixture of natural herbs and spices.

17. (withdrawn) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is derived from low fat milk.

18. (withdrawn) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is a low fat cheese product or artificial cheese.

19. (currently amended) A palatable pharmaceutical composition for administration to companion animals consisting essentially of a pharmaceutical effective amount of a pharmaceutically active agent admixed with one or more excipients and a palatability improving agent, said palatability improving agent being a yeast or yeast hydrolysate, or a combination thereof, said yeast or yeast hydrolysate, or a combination thereof, being present in an amount ranging from abut 2% by weight to about 25% by weight of the pharmaceutical composition.

20. (original) The pharmaceutical composition according to claim 19 wherein the yeast hydrolysate is present in an amount ranging from about 5% to about 20% by weight of the pharmaceutical composition.

21. (original) The pharmaceutical composition according to claim 19 wherein the pharmaceutical has an unacceptable taste and the palatability improving agent is present in amounts sufficient to mask the unacceptable taste of the pharmaceutically active agent.

22. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet, cachet, pill, capsule, troche or chewable tablet.

23. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet.

24. (original) The pharmaceutical composition according to claim 1 or claim 19 wherein the companion animal is a mammal.

25. (original) The composition according to claim 1 or claim 19 wherein the mammal is a dog, cat, or horse.

26. (original) The pharmaceutical composition according to claim 1 or claim 19 wherein the mammal is a dog or cat.

27. (original) The pharmaceutical composition according to claim 1 or claim 19 wherein the palatability improving agent stabilizes the pharmaceutical composition.

28-29. (canceled)

30. (currently amended) A method of making a pharmaceutical composition for oral administration to a companion animal palatable thereto which comprises admixing a pharmaceutically effective amount of the pharmaceutical with a palatability improving agent and a pharmaceutical carrier and orally administering said product to a companion animal, such palatability improving agent being a yeast or a yeast hydrolysate, said yeast

or yeast hydrolysate being present in an amount ranging from about 2% to weight to about 25% by weight of the pharmaceutical composition.

31. (original) The method of claim 30 wherein the palatability improving agent is present in an amount ranging from about 5% to about 20% by weight of the pharmaceutical composition.

32. (original) The method of claim 30 wherein the companion animal is a cat.

33. (original) The method of claim 30 wherein the companion animal is a dog.

34. (original) A method of administering a pharmaceutical composition to a companion animal which comprises administering thereto the pharmaceutical composition according to claims 1 or 19.

35. (original) A method for enhancing compliance with a therapeutic program for companion animals comprising administering to the animal a therapeutically effective amount of the pharmaceutical composition according to claim 1 or claim 19.

36. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet, wherein water is present in an amount less than about 7.5% free or absorbed water content as measured by loss on drying.

37. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet, wherein water is present in an amount less than about 5% free or absorbed water content as measured by loss on drying.

38. (previously presented) The pharmaceutical composition according to claim 1 or 19 in the form of a tablet, wherein the hardness of the tablet is in the range of from about 2.5 kp to 25 kp.

39. (canceled)

40. (previously presented) The pharmaceutical composition according to Claim 1 or Claim 19 wherein pharmaceutical agent is carprofen.

41. (withdrawn) The pharmaceutical composition according to Claim 1 wherein the palatability improving agent is artificial egg.

42. (previously presented) The pharmaceutical composition according to Claim 1 wherein the palatability improving agent is artificial beef.

43. (withdrawn) The pharmaceutical composition according to Claim 1 wherein the palatability improving agent is artificial poultry.

44. (withdrawn) The pharmaceutical composition according to Claim 1 wherein the palatability improving agent is artificial fish.

45. (withdrawn) The pharmaceutical composition according to Claim 1 wherein the palatability improving agent is dairy based.

46. (withdrawn) The pharmaceutical composition according to Claim 1 wherein the palatability improving agent is natural herbs and spices.

APPENDIX B

claims as amended by the after-final amendment (clean copy):

1. (currently amended) A palatable pharmaceutical composition for oral administration to companion animals comprising a pharmaceutically effective amount of a pharmaceutically active agent in combination with a palatability improving agent and a pharmaceutically acceptable carrier, wherein the palatability improving agent is selected from the group consisting of artificial beef, is present in amounts sufficient to make the pharmaceutical composition palatable to the companion animal, and is homogeneously mixed with the pharmaceutically active agent, and wherein the pharmaceutically active agent is carprofen.

2. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 30% voluntary acceptance.

3. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 50% voluntary acceptance.

4. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 80% voluntary acceptance.

5. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 90% voluntary acceptance.

6. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal of about 90% or greater.

7-8. (canceled)

9. (original) The pharmaceutical composition according to claim 1 wherein the pharmaceutically active agent has an unacceptable taste and the palatability improving agent is present in amounts sufficient to mask or improve the unacceptable taste of the pharmaceutically active agent.

10. (original) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is present in an amount ranging from about 0.025% to about 99% by weight of the pharmaceutical composition.

11-12. (canceled)

13. (currently amended) The pharmaceutical composition of claim 19 wherein the palatability improving agent is yeast and is present in an amount ranging from about 2% to about 25% by weight of the pharmaceutical composition.

14. (currently amended) The pharmaceutical composition of claim 19 wherein the palatability agent is yeast present in an amount ranging from about 5% to about 20% by weight of the pharmaceutical composition.

15-18. (canceled)

19. (currently amended) A palatable pharmaceutical composition for administration to companion animals consisting essentially of a pharmaceutical effective amount of a pharmaceutically active agent admixed with one or more excipients and a palatability improving agent, said palatability improving agent being a yeast or yeast hydrolysate, or a combination thereof, said yeast or yeast hydrolysate, or a combination thereof, being present in an amount ranging from abut 2% by weight to about 25% by weight of the pharmaceutical composition, and wherein the pharmaceutically active agent is carprofen.

20. (original) The pharmaceutical composition according to claim 19 wherein the yeast hydrolysate is present in an amount ranging from about 5% to about 20% by weight of the pharmaceutical composition.

21. (original) The pharmaceutical composition according to claim 19 wherein the pharmaceutical has an unacceptable taste and the palatability improving agent is present in amounts sufficient to mask the unacceptable taste of the pharmaceutically active agent.

22. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet, cachet, pill, capsule, troche or chewable tablet.

23. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet.

24. (original) The pharmaceutical composition according to claim 1 or claim 19 wherein the companion animal is a mammal.

25. (original) The composition according to claim 1 or claim 19 wherein the mammal is a dog, cat, or horse.

26. (original) The pharmaceutical composition according to claim 1 or claim 19 wherein the mammal is a dog or cat.

27. (original) The pharmaceutical composition according to claim 1 or claim 19 wherein the palatability improving agent stabilizes the pharmaceutical composition.

28-29. (canceled)

30. (currently amended) A method of making a pharmaceutical composition for oral administration to a companion animal palatable thereto which comprises admixing a pharmaceutically effective amount of the pharmaceutical with a palatability improving agent and a pharmaceutical carrier and orally administering said product to a companion animal, such palatability improving agent being a yeast or a yeast hydrolysate, said yeast or yeast hydrolysate being present in an amount ranging from about 2% to weight to about 25% by weight of the pharmaceutical composition, wherein the pharmaceutical is carprofen.

31. (original) The method of claim 30 wherein the palatability improving agent is present in an amount ranging from about 5% to about 20% by weight of the pharmaceutical composition.

32. (original) The method of claim 30 wherein the companion animal is a cat.

33. (original) The method of claim 30 wherein the companion animal is a dog.

34. (original) A method of administering a pharmaceutical composition to a companion animal which comprises administering thereto the pharmaceutical composition according to claims 1 or 19.

35. (original) A method for enhancing compliance with a therapeutic program for companion animals comprising administering to the animal a therapeutically effective amount of the pharmaceutical composition according to claim 1 or claim 19.

36. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet, wherein water is present in an amount less than about 7.5% free or absorbed water content as measured by loss on drying.

37. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet, wherein water is present in an amount less than about 5% free or absorbed water content as measured by loss on drying.

38. (previously presented) The pharmaceutical composition according to claim 1 or 19 in the form of a tablet, wherein the hardness of the tablet is in the range of from about 2.5 kp to 25 kp.

39-41. (canceled)

42. (previously presented) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is artificial beef.

43-46. (canceled)

APPENDIX C

claims as amended by the after-final amendment (marked-up copy):

1. (currently amended) A palatable pharmaceutical composition for oral administration to companion animals comprising a pharmaceutically effective amount of a pharmaceutically active agent in combination with a palatability improving agent and a pharmaceutically acceptable carrier, wherein the palatability improving agent is selected from the group consisting of ~~artificial egg,~~ artificial beef, ~~artificial poultry, artificial fish, dairy based palatability improving agent and natural herbs and spices, or mixtures thereof,~~ is present in amounts sufficient to make the pharmaceutical composition palatable to the companion animal, and is homogeneously mixed with the pharmaceutically active agent, and wherein the pharmaceutically active agent is carprofen.

2. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 30% voluntary acceptance.

3. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 50% voluntary acceptance.

4. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 80% voluntary acceptance.

5. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 90% voluntary acceptance.

6. (original) The composition of claim 1 wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal of about 90% or greater.

7-8. (canceled)

9. (original) The pharmaceutical composition according to claim 1 wherein the pharmaceutically active agent has an unacceptable taste and the palatability improving agent is present in amounts sufficient to mask or improve the unacceptable taste of the pharmaceutically active agent.

10. (original) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is present in an amount ranging from about 0.025% to about 99% by weight of the pharmaceutical composition.

11-12. (canceled)

13. (currently amended) The pharmaceutical composition of claim [[1]] 19 wherein the palatability improving agent is yeast and is present in an amount ranging from about 2% to about 25% by weight of the pharmaceutical composition.

14. (currently amended) The pharmaceutical composition of claim [[1]] 19 wherein the palatability agent is yeast present in an amount ranging from about 5% to about 20% by weight of the pharmaceutical composition.

15-18. (canceled)

19. (currently amended) A palatable pharmaceutical composition for administration to companion animals consisting essentially of a pharmaceutical effective amount of a pharmaceutically active agent admixed with one or more excipients and a palatability improving agent, said palatability improving agent being a yeast or yeast hydrolysate, or a combination thereof, said yeast or yeast hydrolysate, or a combination thereof, being present in an amount ranging from abut 2% by weight to about 25% by weight of the pharmaceutical composition, and wherein the pharmaceutically active agent is carprofen.

20. (original) The pharmaceutical composition according to claim 19 wherein the yeast hydrolysate is present in an amount ranging from about 5% to about 20% by weight of the pharmaceutical composition.

21. (original) The pharmaceutical composition according to claim 19 wherein the pharmaceutical has an unacceptable taste and the palatability improving agent is present in amounts sufficient to mask the unacceptable taste of the pharmaceutically active agent.

22. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet, cachet, pill, capsule, troche or chewable tablet.

23. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet.

24. (original) The pharmaceutical composition according to claim 1 or claim 19 wherein the companion animal is a mammal.

25. (original) The composition according to claim 1 or claim 19 wherein the mammal is a dog, cat, or horse.

26. (original) The pharmaceutical composition according to claim 1 or claim 19 wherein the mammal is a dog or cat.

27. (original) The pharmaceutical composition according to claim 1 or claim 19 wherein the palatability improving agent stabilizes the pharmaceutical composition.

28-29. (canceled)

30. (currently amended) A method of making a pharmaceutical composition for oral administration to a companion animal palatable thereto which comprises admixing a pharmaceutically effective amount of the pharmaceutical with a palatability improving agent and a pharmaceutical carrier and orally administering said product to a companion animal, such palatability improving agent being a yeast or a yeast hydrolysate, said yeast or yeast hydrolysate being present in an amount ranging from about 2% to weight to about 25% by weight of the pharmaceutical composition, wherein the pharmaceutical is carprofen.

31. (original) The method of claim 30 wherein the palatability improving agent is present in an amount ranging from about 5% to about 20% by weight of the pharmaceutical composition.

32. (original) The method of claim 30 wherein the companion animal is a cat.

33. (original) The method of claim 30 wherein the companion animal is a dog.

34. (original) A method of administering a pharmaceutical composition to a companion animal which comprises administering thereto the pharmaceutical composition according to claims 1 or 19.

35. (original) A method for enhancing compliance with a therapeutic program for companion animals comprising administering to the animal a therapeutically effective amount of the pharmaceutical composition according to claim 1 or claim 19.

36. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet, wherein water is present in an amount less than about 7.5% free or absorbed water content as measured by loss on drying.

37. (original) The pharmaceutical composition according to claim 1 or claim 19 in the form of a tablet, wherein water is present in an amount less than about 5% free or absorbed water content as measured by loss on drying.

38. (previously presented) The pharmaceutical composition according to claim 1 or 19 in the form of a tablet, wherein the hardness of the tablet is in the range of from about 2.5 kp to 25 kp.

39-41. (canceled)

42. (previously presented) The pharmaceutical composition according to claim 1 wherein the palatability improving agent is artificial beef.

43-46. (canceled)